



DEPARTMENT OF HEALTH & HUMAN SERVICES

MBL267

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

November 2, 1999

Telephone: 425-486-8788
FAX: 425-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-12

Ken R. Ashley, President
SeaPac of Idaho
4074 North 2000 East
Filer, Idaho 83328

WARNING LETTER

Dear Mr. Ashley:

On May 13, 1999, the Food and Drug Administration (FDA) conducted an inspection of SeaPac of Idaho located at 4074 North 2000 East, Filer, Idaho. At the conclusion of the inspection, you were presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) 123 - Fish and Fishery Products (HACCP Regulation). 21 CFR 123.16 also requires smoked fish processors to include in their HACCP plan how they are controlling the food safety hazard associated with the formation of *Clostridium botulinum* toxin. A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the smoked trout and salmon products processed by your firm are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR 123.

Your trout products containing a nitrite salt are further adulterated within the meaning of 21 USC 342(a)(2)(c) because they contain a food additive which is unsafe, as defined by 21 USC 348, because its use does not conform to a regulation prescribing safe conditions of use. The regulation applicable to the use of sodium nitrite (21 CFR 172.175) does not provide for the use of sodium nitrite, or any other nitrite salt, as a color fixative or preservative in trout.

1. You are required by 21 CFR 123.8(a) to verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur. However, your firm did not verify the effectiveness of the critical limits set at the brining and smoking critical control points (CCP) to prevent the formation of *Clostridium botulinum* toxin.

In order to do this, we believe that it will first be necessary to set critical limits for maximum fish thickness and to specify in the plan the minimum brine to fish ratio and brine salt concentration necessary to achieve a minimum water phase salt of 3.5% for smoked trout and 3.0% water phase salt for salmon products which contain 100 ppm nitrites.

Your firm provided our investigator with analytical results from 1994 for water phase salt and nitrites. These five-year-old records, by themselves, do not sufficiently demonstrate that your plan is adequate to control *Clostridium botulinum*.

2. You must have a HACCP plan that lists monitoring procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits (21 CFR 123.6⁽⁴⁾). However, your HACCP plan does not list monitoring procedures, and the frequency thereof for the critical control point of receiving and the hazard of chemical-residues (illegally used aquaculture drugs) to ensure that your critical limit is met. Chemical analysis of aquaculture drugs was listed as a monitoring procedure, but, would be more appropriate as a verification procedure. In accordance with 21 CFR 123.9(b) and (c) certificates and verification records must be retained and available for review.
3. You have not met the requirements of 21 CFR 123.6(b) to implement your HACCP plan because you did not have monitoring records to document the brine temperature for product processed on April 5-7, 1999 and refrigeration temperature at the product storage CCP on April 5-7, 1999.
4. The corrective action you specified in your plan at the ingredient measurement, brining, smoking and cold storage CCPs does not meet the requirements of 21 CFR 123.7(b) for corrective actions developed by processors because it does not ensure that the cause of the deviation is corrected.
5. You must maintain sanitation control records that document monitoring and corrections in order to comply with 21 CFR 123.11(c). However, your sanitation control records do not include monitoring and correction for proper labeling, storage, and use of toxic chemicals.

During the previous inspection, on May 19, 1998, and in a letter from the FDA, dated August 28, 1998, you were notified of the same deficiencies described in points numbered 1, 3, and 5 of this letter. During the inspection, and in the letter, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is

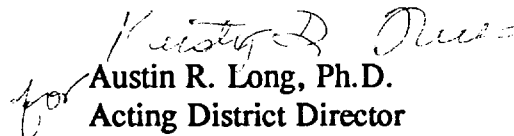
Ken R. Ashley, President
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concerned that in nine months time, your firm has not taken action to correct these deficiencies.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Lisa M. Elrand, Acting Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,


for Austin R. Long, Ph.D.
Acting District Director

Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: ISDA with disclosure statement